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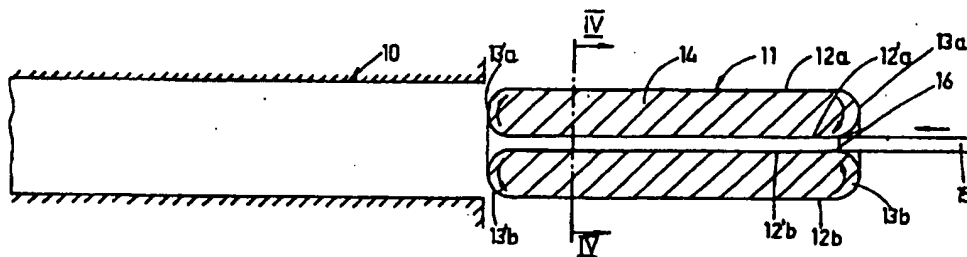
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(57) Abstract

Endoscopic insertion device into a duct, characterized in that it comprises an essentially tubular, endless body (11) defined by a sheath having negligible resistance to deformation and being in substantially distended condition, said body having, in any position thereof, a substantially elongated portion (12a, 12b, 12a', 12b'), bounded by semi-toroidal end portions (13a, 13b, 13a', 13b').

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ENDOSCOPIC DEVICE

Field of the Invention

The present invention relates to a device for introducing into ducts and canals of any kind, particularly but not exclusively of the human body, an active element, such as a means for inspection, cleaning, delivering or draining matter, or carrying out other manipulations. Particularly, it relates to an insertion tube for an endoscopic apparatus.

Background of the invention

In many medical and diagnostic operations it is necessary to introduce an active element into the body of the patient for inspecting and obtaining information on inner parts of the body or for delivering substances into or draining substances from them or for carrying out various manipulations. In the present art, the active element is delivered to the desired points of the duct or canal of the body by means of a catheter, which is pushed into the body from the opening of the duct or canal, to overcome the friction on its walls and the resistance generated by its convolutions and bends. The catheter must be flexible enough to pass the canal's convolutions and yet rigid enough to overcome said friction and resistances. These two contradictory requirements are never fully met by the same catheter: in many cases the catheter is either not flexible enough to pass the convolutions of the canal or not rigid enough to overcome the resistance to its motion and therefore is not effective. In many cases, its insertion is painful.

The most progressive existing devices comprise an insertion tube, having a diameter for instance between 9 and 14 millimeters, which incorporates a much smaller working channel, which, in the case of endoscopes, can be an optical fiber channel, connecting a lens to a camera or other monitoring apparatus. In other cases the working channel may be a conduct for the removal from, or the supply of liquids to, the desired area; or may include means for actuating instruments carried at the forward end of the insertion tube. In spite of the progress made by the art, the existing catheters and probes, are in many cases painful and even dangerous to apply, and in some cases the number of turns in the canal of the patient's body and the distance to which the probe must be delivered make the use of the existing catheters and probes practically impossible.

It is a purpose of this invention to overcome all the drawbacks of the existing endoscopic devices.

It is another object of this invention to provide endoscopic means that are painless to apply and cause no danger or discomfort to the patient.

It is a further purpose of this invention to provide an endoscopic insertion tube which is capable of passing all the convolutions and bends of the inner body's canals.

It is a still further purpose of this invention to provide an endoscopic device that is simple, extremely easy to use and economical.

It is a still further purpose of this invention to provide such a device that is adapted to all the existing endoscope, e.g., for the purpose of inspecting, cleaning, delivering medications, surgical instruments, monitoring devices etc.

It is a still further purpose of this invention to provide an endoscopic insertion tube which eliminates the sliding friction and rubbing contact which accompany the insertion of endoscopes according to the prior art.

Other purposes and advantages of this invention will appear as the description proceeds.

Summary of the invention

The endoscope insertion device according to the invention is characterized in that it comprises an essentially tubular, endless body defined by a sheath having negligible resistance to deformation and being in substantially distended condition, said body having, in any position thereof, a substantially elongated portion bounded by semi-toroidal end portions.

By "essentially tubular body" is meant herein a body defined by two concentric, cylindrical surfaces, an outer and an inner one. As is well known, the term "torus" describes a solid or surface generated by the rotation of a circle about an axis that does not intersect it. The term "semi-toroidal" means herein a body or surface that is one-half of a torus which has been cut along its plane of symmetry. The expressions "substantially elongated portion" and "semi-toroidal end portions" refer to a condition of

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the device in which it is fully extended and located in a elongated canal. In other conditions its shape may be modified because of its easy deformability: for instance, the elongated portion may be bent and/or creased and the semi-toroidal end portions may be creased or otherwise deformed, said deformations causing it to depart from the shape defined by the above expressions. It may be said that the above expressions define the ideal shape of the body defined by the distended sheath.

Because of its structure, the insertion device or insertion tube according to the invention can advance along a canal or duct as its toroidal end portions roll over the inner surface of the canal or duct. In this motion, while the overall shape of the device remains unchanged, any specific segment of the sheath will successively occupy different positions of the device surface, and thus, e.g., a segment which constitutes a semi-toroidal end portion will become a part of a elongated portion, and vice versa, as will be more fully explained hereinafter. In this sense the tubular body of the device is "endless" and the term "endless" should be so construed: viz. to signify that no portion of the device permanently constitutes an end, in the sense that end portions and intermediate portions change the ones into the others as the device progresses.

In a preferred embodiment of the invention, its essentially tubular, endless body is defined by a cylindrical sheath having two ends and folded upon itself, said two ends being in connected positioned relationship. The connected positioned relationship may be obtained by inverting one end of the tube towards the other and then connecting the two ends directly to one another, but is preferably obtained by connecting both of them to another component of the device.

In another preferred embodiment, the insertion device further comprises a flexible actuating rod, providing a working channel, having significant resistance to compression, and having a diameter that is small enough for said rod to be introduced into the space defined by the inner surface of the tubular body. The actuating rod is preferably connected to said inner surface.

The actuating rod may carry at its forward end the active element of the endoscope, which may be any element known in the art, and in that case it provide a working channel housing the elements, if any are needed, connecting the active element to the visualizing, monitoring or console unit. By "forward end" is meant the end that is inserted into the patient's body when the device is in operation and by "rear end" is meant the end that is not so inserted. Said actuating rod is long enough to carry the active element to the zone of the body on which it is desired to operate. However, the actuating rod may only constitute a passage for liquids, e.g. liquids introduced into the body of a patient or drained from it

The sheath is made of a thin film of an elastomeric or plastomeric material. Examples of such materials are natural or synthetic rubber, polyurethane, polyolefins, Teflon, PVC, etc. The thickness of the sheath may be, for example, from 10 to 1000 μm . The surface of the sheath is preferably smooth and may be provided on its surface with friction reducing matter, permanently or removable applied to it, or other substances having medicinal value.

The actuating canal is preferably tubular, with an annular cross-section, and made of a flexible but non-elastic matter, in particular plastics.

The means for keeping said essentially tubular body in substantially distended condition may be of any nature. Preferably it consists of a fluid, liquid or gas, and more preferably of water, to which the sheath is impermeable. It may comprise both a liquid and a gas. It may also consist of a solid in particulate form, since the body need not be fully distended but may be distended only to a substantial degree, to permit it to operate as will be described hereinafter. Examples of such a solid filling are fillings of expanded polystyrene granules or of metal balls in combination with liquids.

The method of the insertion of an endoscopic device into a duct, according to the invention, comprises:

- a- providing an essentially tubular, endless body defined by a sheath having negligible resistance to deformation, said body having, in any position thereof, a substantially elongated portion bounded by semi-toroidal end portions;
- b- maintaining said sheath in substantially distended condition; and
- c- exerting a forward thrust on said body, preferably by means of an actuating rod providing a working channel, whereby to cause said semi-toroidal ends to progress into and along said duct by rolling on its inner surface.

In an embodiment of the invention, the method comprises attaching an active element to the forward end of said actuating rod.

Said essentially tubular, endless body having semi-toroidal end portions can be prepared, e.g., by providing a cylindrical sheath, folding the same over itself to create a tubular body, and juxtaposing and connecting the two ends of said sheath.

Furthermore, said tubular endless body may be provided in a non rectilinear shape, e.g., banana shape or a shape comprising two or more arcs.

Brief description of the drawings

In the drawings:

Figs. 1 to 3 are axial cross-sections of an insertion tube according to an embodiment of the invention, in various stages of its operation;

Fig. 4 is a transverse cross-section, at an enlarged scale, of the said tube, taken in plane IV-IV of Fig 1;

Figs. 5 to 7 are axial cross-sections of insertion tubes according to other embodiments of the invention;

Figs. 8 and 9 illustrate in axial cross-sections an insertion tube that does not comprise an actuating rod;

Fig. 10 illustrates in axial cross-section an insertion tube for drainage purposes;

Fig. 11a, b, c and d schematically illustrate a manner of making the substantially tubular, endless body of an insertion tube;

Fig. 12 illustrates in schematic axial cross-section and part view an insertion tube according to another embodiment of the invention;

Fig. 13 illustrates a cross-section of the drainage tube of Figure 12; and

Fig. 14a, b and c illustrate a preferred embodiment of the drainage tube.

Detailed description of preferred embodiments

The principle on which the endoscope insertion tube according to the invention operates is illustrated in Figs. 1, 2, 3 and 4. Fig. 1 illustrates the insertion tube in axial cross-section prior to its insertion into a body canal. Said canal is schematically indicated at 10 and, for purpose of illustration, is shown as smooth and straight, although of course a canal in a body will be neither. Likewise, the insertion tube is shown as fully distended and straight, having a rectilinear axis, although in its use it will bend and may locally fold and/or collapse, in order to follow the configuration of the canal in which it is being introduced. Its transverse cross-section as shown in Fig. 4.

The sheath that defines the essentially tubular, endless body of the insertion device, according to this embodiment of the invention, is generally indicated at 11. In any position of the insertion tube, its axial cross-section comprises, as seen in Fig. 1, four rectilinear segments, two outer ones 12a-12b and two inner ones 12'a-12'b, parallel to one another and to the axis of the insertion tube, and four semi-circular ends, two rear ones 13a-13b and two forwards ones 13'a-13'b, joining said segments at both their ends. Segments 12a and 12b are the cross-section of the outer cylindrical surface of the tubular body defined by sheath 11 and segments 12'a and 12'b are the cross-section of its inner surface. In the condition illustrated in Fig. 1 to 3, the sheath is kept distended by a filling 14 and it is straight, since it is being introduced into a straight duct of constant cross-section. In its use, however, it may be introduced into ducts that are

bent and convoluted and the cross-section of which may not be constant. Therefore it will bend, fold and crease, as has been said. Such deformations may reduce its inner volume to some extent, and therefore, if an incompressible fluid, such as water, is used in the filling, it is desirable to provide some compressibility, e.g. by adding to it an amount of gas in order or by other means hereinafter mentioned. Numeral 15 indicates an actuating rod. Actuating rod 15 is joined to the sheath about its forward end, as indicated at 16. In Figs. 1 to 3, no active element is shown as attached to rod 15, which is illustrated in Fig. 4 as a tube, defining a working channel 17 that is merely an empty passage.

If now the insertion tube in the condition shown in Fig. 1 is engaged with the opening of canal 10, and actuating rod 15 is pushed forward, the overall shape of the insertion tube does not change, but the various portions of sheath 11 become displaced with respect to one another and replace one another within said overall shape, and as a result the insertion tube advances within canal 10, as shown in Figs. 2 and 3, without sliding over its inner surface. Thus, e.g., the portions that constituted section 12a in Fig. 1 will move to semi-circular portion 13a and then to segment 12'a, and the portions that constituted section 12b in Fig. 1 will move to semi-circular portion 13'b and then to segment 12'b.

In the position of Fig. 2, actuating rod 15 and point 16 have reached half way along the insertion tube and this latter has advanced within said canal by one half of its length. In the position of Fig. 3, actuating rod 15 has moved completely forward and point 16 is close to the forward end of the insertion tube. In this position, the part of the sheath that constituted

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the inner cylindrical surface of the tubular body now constitutes the forward semi-circular toroidal surface and most of the outer cylindrical surface of the tubular body, while the part of the sheath that constituted the outer cylindrical surface of the tubular body now constitutes the rear semi-circular toroidal surface and most of the inner cylindrical surface of the tubular body. For the most part, though not entirely, the essentially tubular body has been turned inside-out. Meanwhile, the insertion tube has progressed along duct 10 by a distance equal to the length of the rectilinear segments 12a, 12'a, 13a and 13'a. The same displacements will occur, in reverse order, when the insertion tube is withdrawn from the duct.

The volume between the outer and the inner cylindrical surfaces of the tubular body of the insertion tube has not changed, since this latter is kept substantially distended by the filling. However, the insertion tube has advanced along the canal 10 without sliding over or rubbing against its surface: it has advanced, one may say, with a rolling motion, as its semi-toroidal ends have rolled over the canal inner surface. This can be illustrated by considering point P in Fig 2. As the insertion tube advances to the position of Fig. 3, point P will move along the dotted line 18 until it reaches position P' on the inner surface of canal 10. Concurrently, point Q will move along the dotted line 19 until it reaches position Q'. The distances P"-P' and Q"-Q' are equal to the length of the semi-circles 13 and 13'. Therefore the insertion tube has advanced along canal 10 by a distance equal to said length without sliding over the surface of said canal. One may say that it has rolled over said surface, as well as over the actuating rod, and that any friction generated by its motion is a rolling friction.

While Figs 1 to 4 have illustrated the principle of the operation of the insertion tube according to the invention, Fig 5 shows an endoscope including such an insertion tube. Numeral 20 designates the duct into which the endoscope is inserted. Numeral 21 generally indicates the sheath that defines the essentially tubular, endless body of the insertion device, according to this embodiment of the invention. A filling of any suitable kind will be provided in sheath 21 and is not shown in the drawing. Sheath 11 will include a Numeral 22 designates the actuating rod. The sheath is connected to rod 22 at 26. Rod 22 is hollow and carries inside it the working channel, which may be an optical fiber channel 24. Numeral 27 designates the active element, in this case an optical device, e. g. a lens or a TV camera, adapted for inspecting the inside of duct 20 and storing or/and transmitting information thereon.

Fig. 6 shows an insertion tube 40 which is provided with a gas cushion 41, to maintain within limits the pressure within the liquid 42 which fills the sheath 43. The compressibility of the gas cushion permits the insertion tube to be deformed and to decrease its inner volume without generating excessive inner pressure that might cause permanent dilatation and even failure of the sheath.

Fig. 7 shows an embodiment in which the pressure within the liquid filling 47 of an insertion tube 45 is created and controlled hydrostatically by means of a feed tube 46.

Figs. 8 and 9 illustrate in schematic axial cross-section a device which does not include an advancing rod. In Fig. 8 the device is seen at the stage in which it is about to be introduced into a duct 50. The device is similar to that of Figs. 1 to 3 and comprises an essentially tubular body having an outer cylindrical surface generically indicated at 51 and an inner cylindrical surface generally indicated at 52. A filling of any suitable kind will be provided within said tubular body and is not shown in the drawing. Additionally, it comprises a head 53, which may be an optical device, such as a lens or a TV camera, which is located in the rear of the tubular body and is connected thereto, such as at 54. The tubular body is introduced into duct 50 and progresses along the same because the head 53 is urged forwards, possibly by means of a separate rod or the like, not shown, or even by an operator's finger, or by the application of a thrust in any other way.

In the condition of Fig. 9, head 53 has reached the forward end of the device and is able to inspect the inside of duct 50 and to register and/or convey information. Thereafter, the entire device may be withdrawn from the duct, and head 53 can continue to register information. If the information is to be transmitted continuously to a terminal, head 53 must be provided with a transmission channel, which is not shown in the figure and may be of any convenient kind.

Fig. 10 illustrates a further embodiment of the invention, in which the insertion device is used for cleaning a duct, in general before inspecting it. The duct may be, e.g., part of a patient's intestine, and is indicated by 60 in Fig. 10. It contains matter to be removed, e.g., as indicated at 61. For

this purpose, an insertion tube, comprising an essentially tubular body generally indicated at 62, is provided. Said tubular body is essentially similar to that of Figs. 1 to 3, and is connected at 63 to an advancing pipe 64. A filling of any suitable kind will be provided within it and is not shown in the drawing. Advancing pipe 64 is connected at its rear end to a container 65 for receiving the drainage from duct 60. A tube 66 is passed through pipe 64 and is connected at its rear end to a source of liquid, e.g., water, not shown. Water or other liquid is thus conveyed through tube 66, through a spray head 67, to the inside of duct 60 to impinge as a spray indicated at 68, on the mass of matter 61. After impinging on said mass, it is deflected back as indicated by arrows 69 and is drained out through the gap between pipe 64 and tube 66, entraining part of the matter 61 and conveying it to container 65. Cleaning duct 60 is thus accomplished, possibly as a preliminary to an inspection thereof.

Fig. 11a to 11d schematically shows a manner of making an essentially tubular, endless body from a cylindrical sheath. Said sheath is shown at 70 in Fig. 11a. It is bent back upon itself, as shown at Fig. 11b, to form an outer cylinder 71 and an inner cylinder 72 connected by semi-toroidal surface 73. The space between cylinders 71 and 72 may then be filled with a convenient filling substance, which in the embodiment illustrated is a liquid, as shown at 74 in Fig. 11c. Inner tube 72 is then bent outwardly over outer cylinder 71, as shown in Fig. 11d, to form another semi-toroidal surface 75 and is then connected to outer cylinder 71, as shown at 76, by any convenient means, such as by welding or by means of an adhesive. The resulting substantially tubular, endless body, which is designated in Fig. 11d by 70' is partially filled with liquid 74 and a space 77 filled with

air or other gas remains, in the embodiment illustrated, to guarantee that the body 70' has the required compressibility. Compressibility can be achieved, in general, as has been exemplified, by using a compressible filling or by using a filling that is partly compressible and partly incompressible (e.g., partly gas and partly liquid) or by keeping the filling in constant communication with a head of fluid.

Fig. 12 schematically illustrates a further embodiment of the invention, comprising an endoscope and a drainage tube. Numeral 80 designates the duct into which the endoscope is inserted. Number 81 generally indicates the sheath that defines the essentially tubular, endless body of the insertion device, similarly to the previously described embodiments of the invention. A filling of any suitable kind is provided within sheath 81, and is not shown in the drawing. Number 90 indicates an actuating rod, through which passes a duct 82 connected at its end to a camera 83, which duct 82 houses the channel through which the power supply and the optical signals produced by the camera are conveyed to a conventional outside station, that need not be described. Rod 90 is connected to sheath 81 at any convenient point, such as 86.

The insertion tube of Fig. 12 further comprises a drainage tube 89 through which passes the duct 82. The drainage tube is shaped in cross-section as shown in Fig. 13, which is at an enlarged scale, the thickness of the drainage tube wall being exaggerated for illustrative purposes. Tube 89 is provided with an incision 91. A wedge 92 (see Fig. 12) is connected to the camera 83 in any convenient way, e.g., as shown, via a sleeve 93.

The endoscope is used as described with reference to the previous embodiments. At the beginning of its use, tube 89 is incised as shown in Fig. 13 and is slit open at the beginning of the bend, to permit the sleeve 93, and the duct 82 to leave the drainage tube 89. As the actuating rod 90 pushes the endoscope inside the duct 80, its essentially tubular, endless body 81 tends to carry with it the drainage tube 89. However the end of said drainage tube is outside duct 80, as shown in Fig. 12. Tube 89 is adhesively connected to the sheath 81 in the position 97 as shown in the figure. This causes the bend of drainage tube 89 to progress farther and farther away from the open end of said tube. The wedge 92 being in contact with the incision 91 of the drainage tube progressively lengthens the slit of said tube, as shown at 96 so that the camera 83 will be carried forward with the body 81 of the insertion device, while the drainage tube remains in place as shown in Fig. 12. Any liquid contained within the duct 80 enters the drainage tube through its slit 93, to drain out of it, as schematically shown at 95.

This embodiment has the additional advantage that the presence of the wedge 92 and its engagement with the edges of the slit of the drainage tube prevents the camera from rotating while the endoscope is in use and causes it invariably to maintain the desired orientation.

It is apparent that structural means other than wedge 92 could be easily devised by skilled persons in order to prolong the slit of the drainage tube and/or to maintain the orientation of the camera.

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According to a preferred embodiment of the invention, a thick tube 89 is provided. However, although thick tubes have improved strength, which make it possible to cut them along their length instead of just weakening them (see 91, Fig. 13), they lack flexibility. In order to improve the flexibility of the drainage tube, which is preferably tubular, a plurality of radial cuts positioned along its length are provided. The cuts are narrow, i.e., they do not involve a substantial removal of material from the body of the drainage tube when made. Figure 14a illustrates said embodiment, where numeral 89 indicates the drainage tube and numerals 100 and 101 indicate said radial cuts and longitudinal cut, respectively. Figures 14b and 14c illustrate said embodiment in cross section view.

One of the important advantages of using a drainage tube is that it protects duct 82 from being compressed by sheath 81, thereby allowing camera 83 to be desirably positioned during the insertion process.

While embodiments of the invention have been described by way of illustration, it will be apparent that the invention may be carried out by persons skilled in the art with many modifications, variations and adaptations, without departing from its spirit or exceeding the scope of the claims.

CLAIMS

1. Endoscopic insertion device for insertion into a duct, characterized in that it comprises an essentially tubular, endless body defined by a sheath having negligible resistance to deformation and being in substantially distended condition, said body having, in any position thereof, a substantially elongated portion bounded by semi-toroidal end portions.
2. Insertion tube according to claim 1, wherein the essentially tubular, endless body is defined by a cylindrical sheath having two ends and folded upon itself, said two ends being in connected positioned relationship.
3. Insertion tube according to claim 2, wherein the connected positioned relationship is obtained by inverting one end of the tube towards the other and then connecting the two ends directly to one another.
4. Insertion tube according to claim 2, wherein the connected positioned relationship is obtained by connecting the two ends to another component of the device.
5. Insertion tube according to claim 1, further comprising a flexible actuating rod, providing a working channel, having significant resistance to compression, and having a diameter that is small enough for said rod to be introduced into the space defined by the inner surface of the essentially tubular body.
6. Insertion tube according to claim 5, wherein the actuating rod carries at its forward end an active element.

7. Insertion tube according to claim 5, wherein the actuating rod provides a working channel housing the elements, if any are needed, connecting the active element to an outside unit.
8. Insertion tube according to claim 5, wherein the actuating rod constitutes a passage for the introduction of liquids into the duct or/and drainage of liquids therefrom.
9. Insertion tube according to claim 1, wherein the sheath is made of a thin film of an elastomeric or plastomeric material.
10. Insertion tube according to claim 9, wherein the sheath is made of a material chosen from among natural or synthetic rubber, polyurethane, polyolefins, Teflon, and PVC.
11. Insertion tube according to claim 1, wherein the sheath has a thickness, from 10 to 1000 μm .
12. Insertion tube according to claim 1, wherein the actuating canal is tubular, with an annular cross-section, and made of a flexible but non-elastic matter.
13. Insertion tube according to claim 1, comprising means for keeping the essentially tubular body in substantially distended condition.
14. Insertion tube according to claim 1, wherein the means for keeping the essentially tubular body in substantially distended condition

comprise a filling made of a substance chosen from among liquids or/and gas, to which the sheath is impermeable.

15. Insertion tube according to claim 1, wherein the means for keeping the essentially tubular body in substantially distended condition comprise a solid in particulate form.

16. Insertion tube according to claim 5, further comprising a drainage tube which is folded over the forward end of the tube, when the same is in operation, and extends with one end to the outside of the duct into which the insertion tube is inserted, said drainage tube being split open about the region at which it is folded over said forward end of the insertion tube, to allow liquid or gas contained in the duct to drain out from said one end.

17. Insertion tube according to claim 16, further comprising a camera and a channel through which the signals from said camera are transmitted, said camera being carried at the forward end of the insertion tube and said channel extending through the drainage tube and extending outwardly from it in the region where said drainage tube is split open, when the insertion tube is inserted into the duct.

18. Insertion tube according to claim 16, wherein the drainage tube has a longitudinal incision in the outer portion of its wall, and a wedge is connected to the camera for splitting the drainage tube open about the region which is folded over the forward end of the insertion tube.

19. Insertion tube according to claim 16, wherein the drainage tube has a longitudinal cut and a plurality of radial cuts positioned along its length.

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20. Method of inserting an endoscopic device into a duct, which comprises:
a- providing an essentially tubular, endless body defined by a sheath having negligible resistance to deformation, said body having, in any position thereof, a substantially rectilinear portion bounded by semi-toroidal end portions;
b- maintaining said sheath in substantially distended condition; and
c- exerting a forward thrust on said body, whereby to cause said semi-toroidal ends to progress into and along said duct by rolling on its inner surface.

21. Method according to claim 20, wherein the forward thrust is exerted by means of an actuating rod.

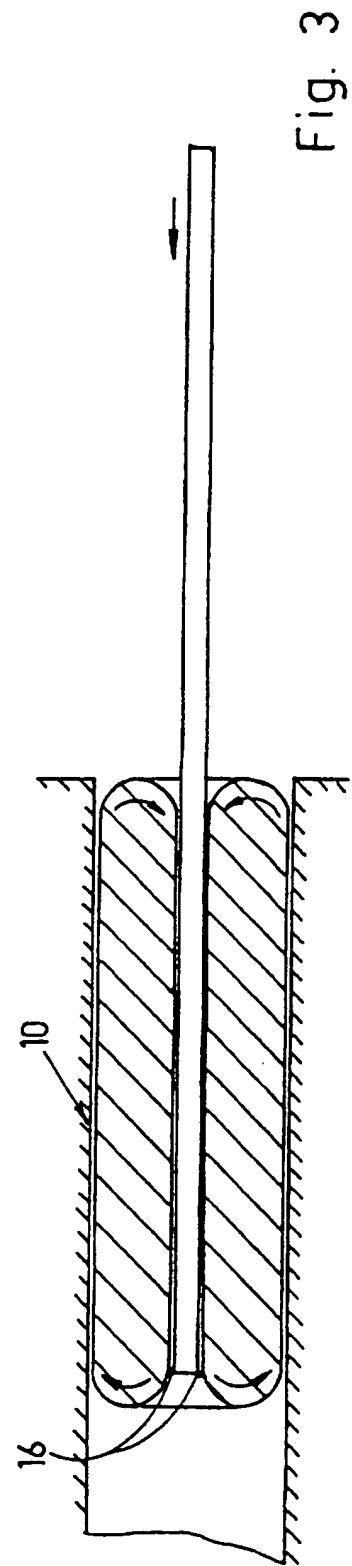
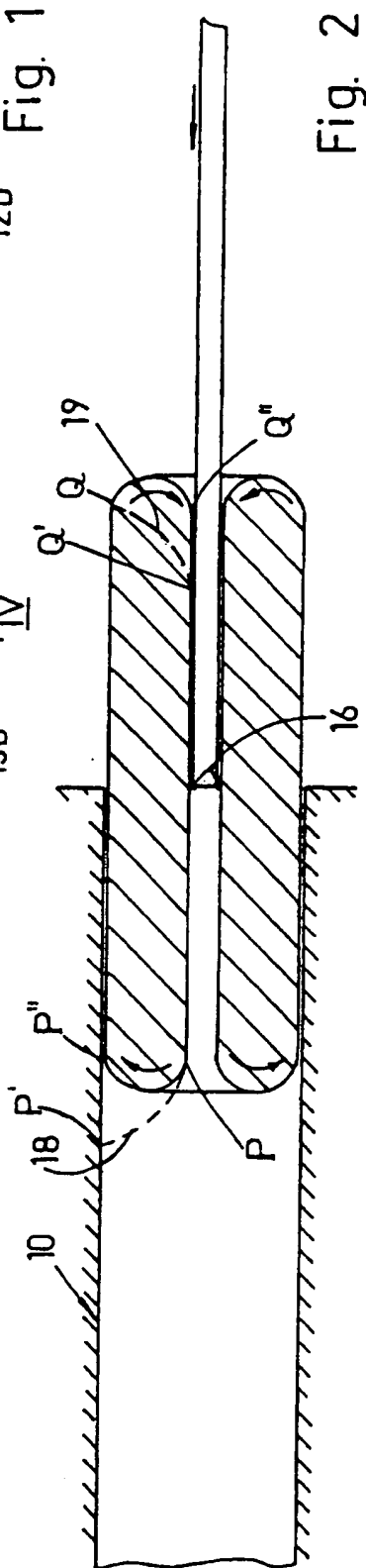
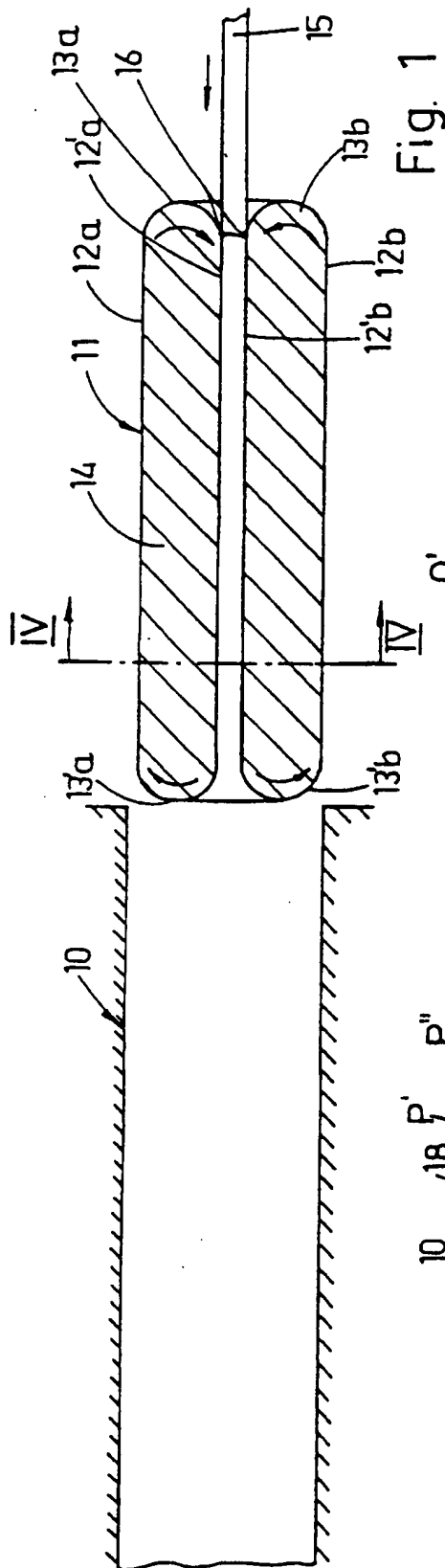
22. Method according to claim 21, further comprising attaching an active element to the forward end of the actuating rod.

23. Method according to claim 20, further comprising making the essentially tubular, endless body having semi-toroidal end portions by providing a cylindrical sheath, folding the same over itself to create a tubular body, and juxtaposing and connecting the two ends of said sheath.

24. Insertion tube according to claim 1, wherein the essentially tubular, endless body is defined by a cylindrical sheath, folded over itself to create a tubular body and having its two ends juxtaposed and connected.

25. Endoscopic insertion device for insertion into a duct, substantially as described and illustrated.

26. Method of inserting an endoscopic device into a duct, substantially as described and illustrated.



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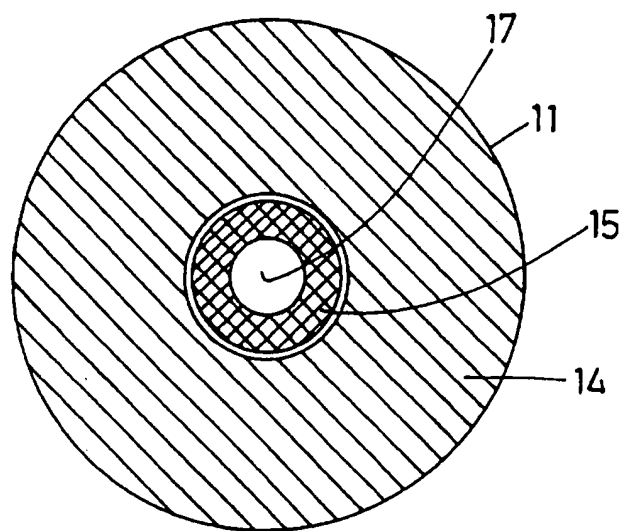


Fig. 4

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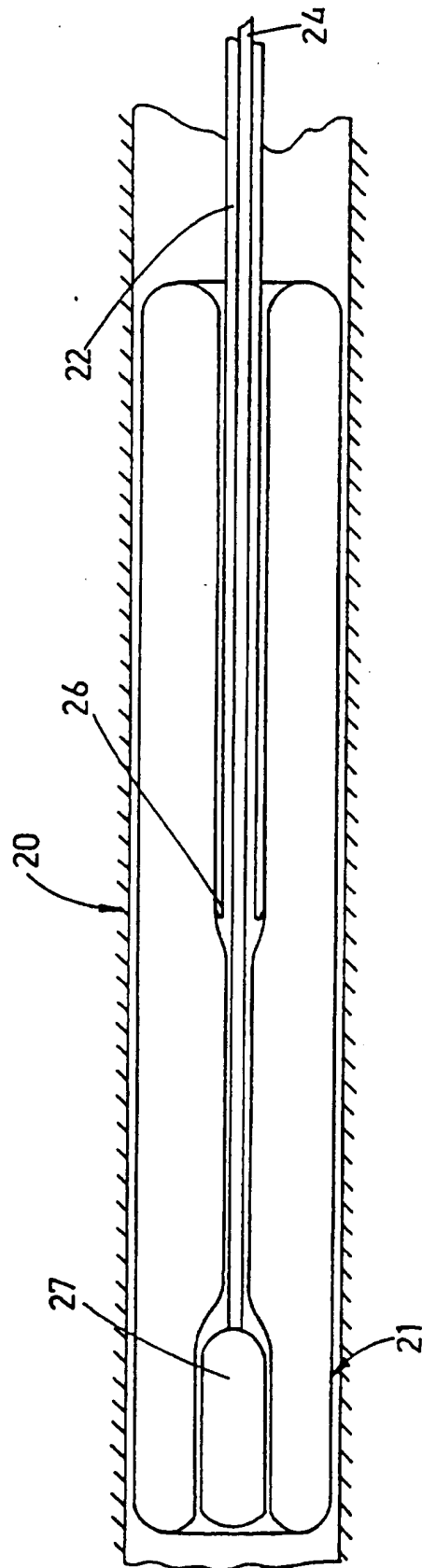


Fig. 5

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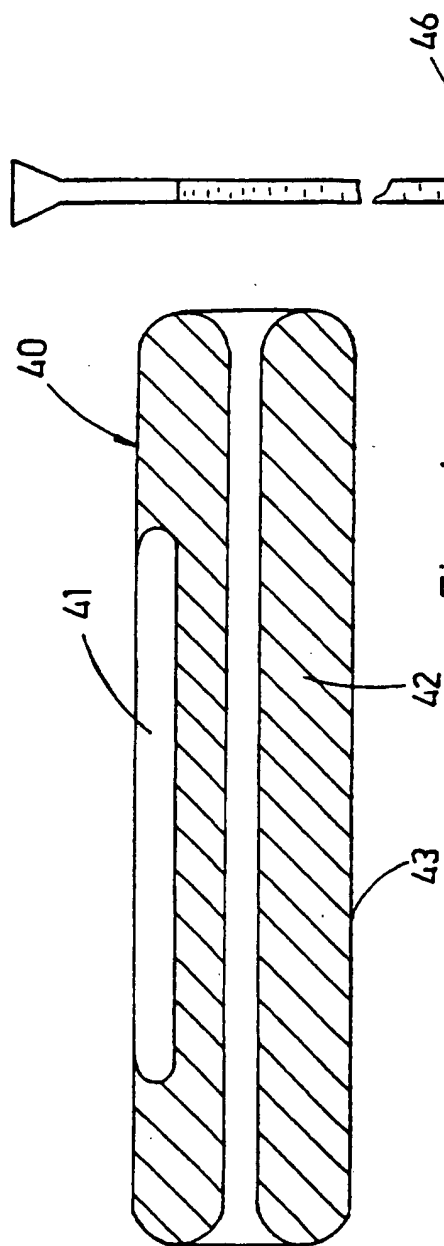


Fig. 6

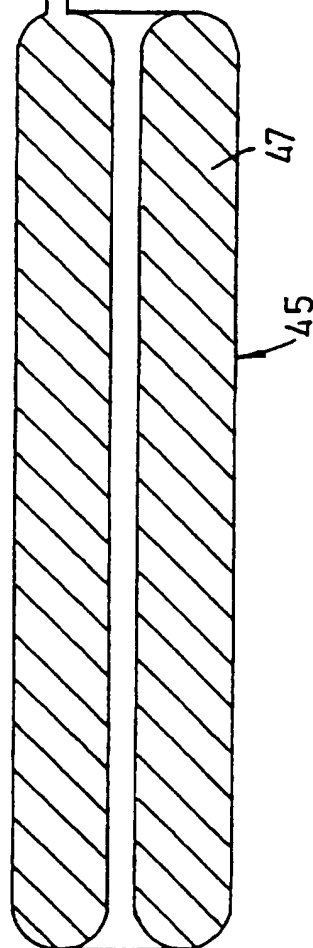


Fig. 7

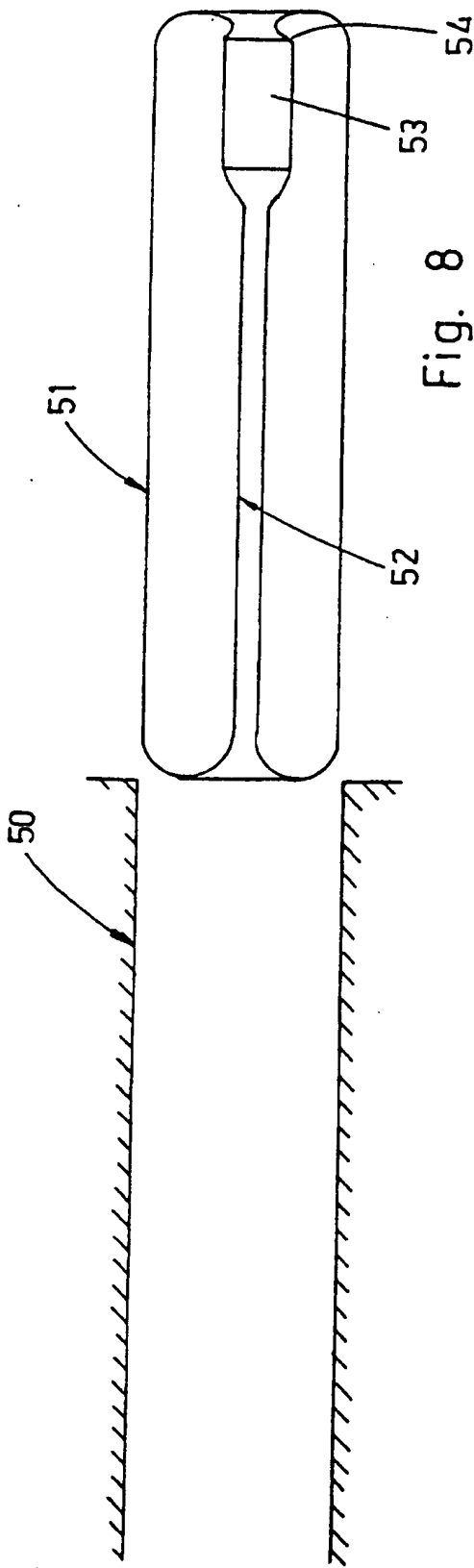


Fig. 8

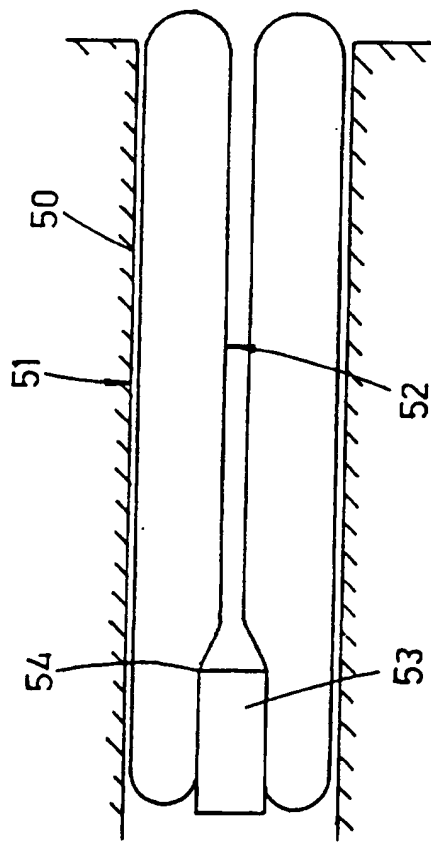


Fig. 9

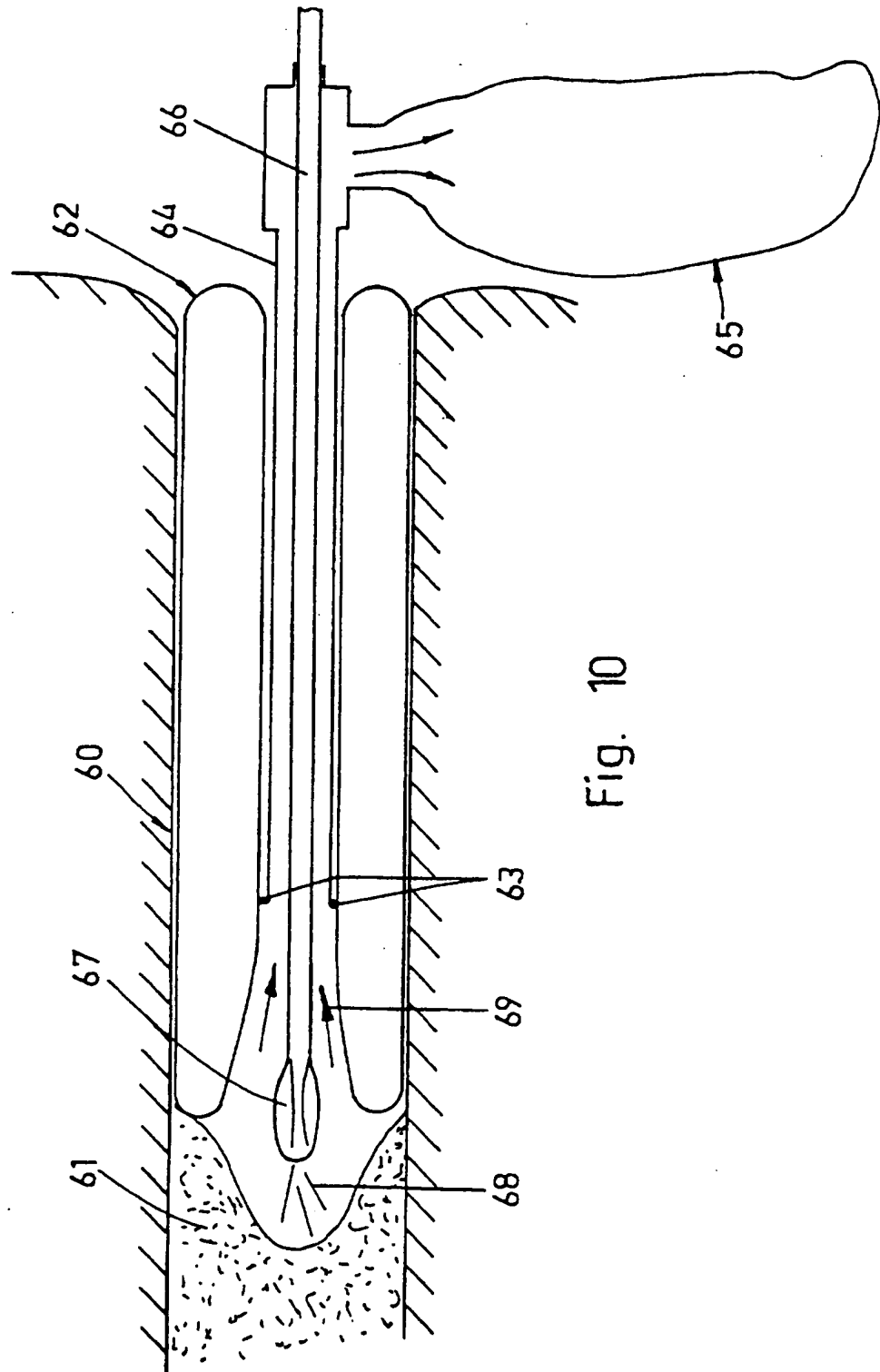


Fig. 10

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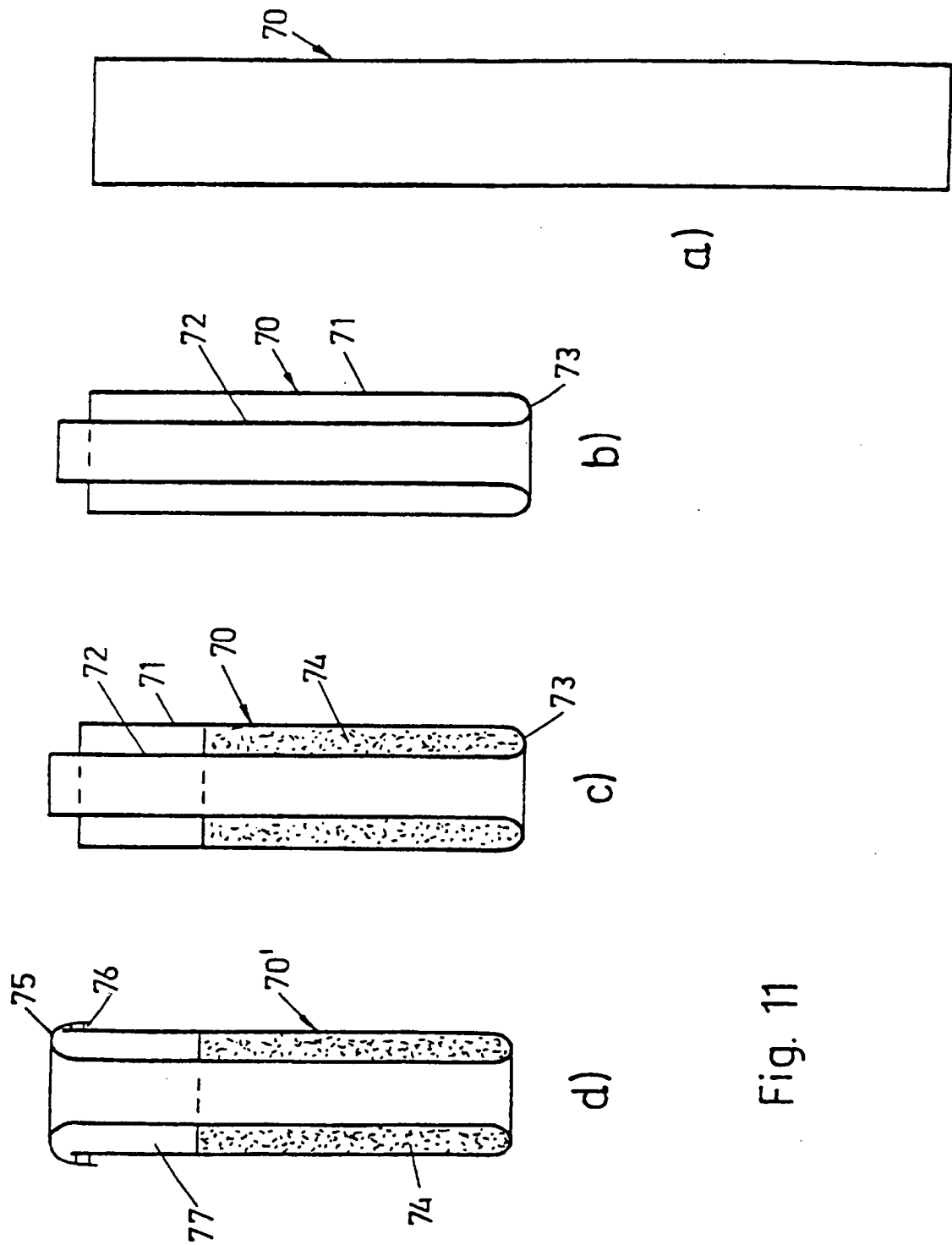


Fig. 11

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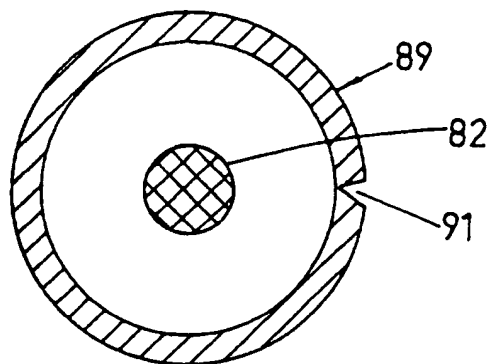


Fig. 13

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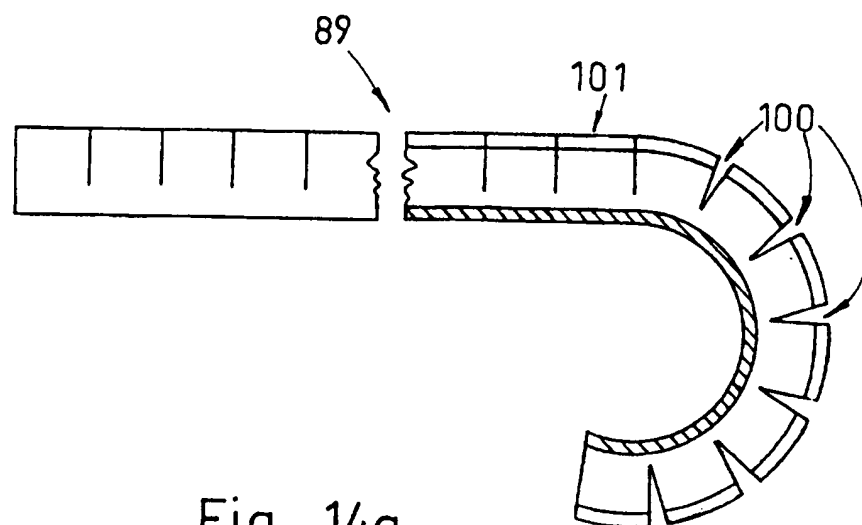


Fig. 14a

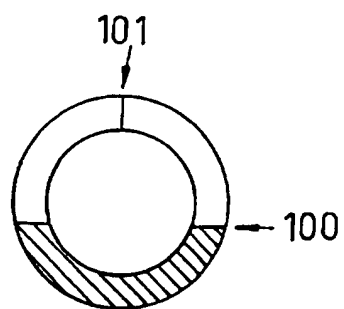


Fig. 14c

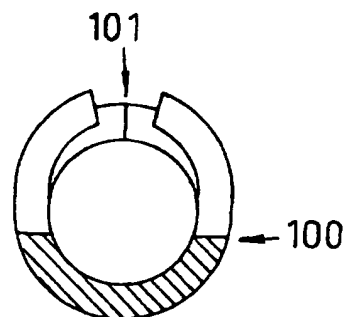


Fig. 14b

INTERNATIONAL SEARCH REPORT

Intern: 1 Application No
PCT/IL 97/00077

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B1/00 A61M25/01

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| X | US 5 045 070 A (R.GRODECKI ET AL) 3 September 1991 | 1,2,24, 25 |
| A | see column 1, line 5 - line 13 | 5,7,9 |
| A | see column 3, line 9 - column 4, line 12 see column 4, line 65 - column 5, line 4 see column 6, line 31 - line 62 --- | 12-14,17 |
| A | US 4 066 070 A (M.UTSUGI) 3 January 1978 | 1,5,7,9 |
| A | see column 1, line 6 - line 46 | 10,12-14 |
| A | see column 2, line 51 - column 5, line 2 --- | 25 |
| A | WO 80 01353 A (J.E.HALL) 10 July 1980 | 1,9 |
| A | see abstract; figure 1 | 13-16 |
| A | see page 3, line 17 - page 4, line 35 see page 9, line 13 - line 29 see page 11, line 23 - page 12, line 2 see page 12, line 27 - line 36 ----- | 24,25 |

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

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- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search

3 July 1997

Date of mailing of the international search report

17. 07. 97

Name and mailing address of the ISA

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Authorized officer

Geffen, N

INTERNATIONAL SEARCH REPORT

International application No.

PCT/IL 97/00077

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 20-23, 26
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No

PCT/IL 97/00077

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|----------------------------|---------------------|
| US 5045070 A | 03-09-91 | NONE | |
| US 4066070 A | 03-01-78 | DE 2629828 A | 13-01-77 |
| WO 8001353 A | 10-07-80 | US 4324262 A | 13-04-82 |
| | | EP 0020756 A | 07-01-81 |